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10/520,349	09/12/2005	Atsushi Nagasawa	0230-0219PUS1	5681	
2392 7590 BIRCH STEWART KOLASCH & BIRCH PO BOX 747			EXAM	EXAMINER	
			BADR, HAMID R		
FALLS CHURCH, VA 22040-0747			ART UNIT	PAPER NUMBER	
			1794		
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Please find below and/or attached an Office communication concerning this application or proceeding.

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Application No. Applicant(s) 10/520,349 NAGASAWA, ATSUSHI Office Action Summary Examiner Art Unit HAMID R. BADR 1794 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 08 December 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 16-24.27.31 and 32 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 16-24, 27, 31-32 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/S5/08)
 Paper No(s)/Mail Date ______.

Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application

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DETAILED ACTION

Applicants' amendment file on 12/8/2008 is acknowledged.

Claims 16-24, 27, and 31-32 are being considered on the merits.

Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 2. Claim 16-24 and 31 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new limitation to claim 1 regarding the fermentability is not supported by the specification given that while there is support in Table 6 to recite specific values of fermentability of Baker's yeast strain in low sugar dough and high sugar dough, there is no support to broadly recite that the yeast has fermentability of "at least 83.6 per 30 g" of a high sugar bread dough and a fermentability of "at least 92.4 per 30 g" of a low sugar bread dough which includes all amounts of fermentability above 83.6 and 92.4 for which there is no support in the present specification.
- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- Claims 16-19, 21-22, and 31-32 are rejected under 35 U.S.C. 112, second
 paragraph, as being indefinite for failing to particularly point out and distinctly claim the
 subject matter which applicant regards as the invention.
- 3. Claims 16 is indefinite for "fermentability of at least 83.6 per 30g" and "fermentability of at least 92.4 per 30g". It is unclear what is meant by these phrases. It is not clear what the applicant regards as the invention. Should those values indicate the volume of carbon dioxide evolved under the conditions of test, such phrases should include the nature of the gas (i.e. carbon dioxide) and the gas volume produced per 30 g of dough.
- 4. Claim 32 is indefinite for "a weak offensive taste and odor characteristic of yeast". It is unclear what is meant by the phrase. It is not clear what the applicant regards as the invention. These terms are subjective terms and "offensive" to one individual is not necessarily offensive to another. It is not clear what the applicant regards as the invention. It is unclear what is meant by "characteristic". It is not clear what the applicant regards as the invention.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claims 16-19, 21-22, 25, 27, 29, 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakagawa et al. (1994, Construction from a single parent of baker's yeast strains with high freeze tolerance and fermentative activity in both lean and sweet doughs; hereinafter R1).

- R1 studies the hybridization of spores of Saccharomyces cerevisiae (commercial baker's yeast) to construct a baker's yeast which is freeze-tolerant and has fermentative activity in both lean and sweet doughs (Abstract).
- R1 teaches determining the mating types to be used for their hybridization process (Page 3500, Col. 1, Determination of mating type).
- 9. R1 discloses the process of construction of hybrids. The isolated haploid strains showing opposite mating types are crossed by mixing in liquid medium. After the hybridization process, isolated strains are checked for their sporulation ability. Spore forming isolates are considered hybrids. (Page 3500, Col. 1, construction of hybrids)
- R1 gives details of dough ingredients for lean, regular and sweet doughs. A
 commercial hard wheat flour is used having 12% protein and 0.36% ash (Page 3500,
 Col. 1 ingredients of doughs and Table 1).
- 11. Given that R1 discloses the suitability of the developed strain of yeast for lean, regular and sweet doughs, it is clear that the fermentability of such doughs will be in the same range as presently claimed.
- R1 teaches the dough raising test by measuring the carbon dioxide evolved after
 hours at 30°C. (Page 3500, Col.1 dough raising test)
- 13. R1 explains the frozen dough system where the prepared doughs are stored at

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-20°C for 1 week. After the freezing period, the thawed dough is placed in a bottle of Fermograph and the dough raising activity is measured for 2 hours. (Page 3500, Col. 1 Frozen dough system)

- 14. R1 indicates that it is possible to obtain strains with more improved qualities such as leavening ability and freeze tolerance than the commercial baker's yeast now available. (Page 3502, Col. 1, lines 13-17)
- 15. Low concentration of isobutyric acid is inherent in the Saccharomyces cerevisiae baker's yeast because all varieties of bread prepared with this yeast have fresh baked aroma and flavor and there is no bread known to have bad taste or aroma. On the other hand the instant specification states that "Although substances responsible for the offensive taste and odor characteristic of yeast are composed of a wide variety of compounds and are difficult to restrict to one kind of compound, it is estimated that isobutyric acid which is known as a linear fatty acid having a foul odor <u>may</u> be one of the causative substances." (page 8, lines 14-19). Therefore, the role of isobutyric acid is not pivotal for the limitation of claim 16.

Response to Arguments

Applicant's arguments have been thoroughly reviewed. They are not deemed persuasive for the following reasons.

 Applicant argues that verbatim support for claim terms in not required for U.S. patent specifications. Application/Control Number: 10/520,349

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a. It is agreed that verbatim support for claim terms is not required of U.S. patent specifications. However, there must be some kind of description in the specification to have the same effect of the terminology in the claims.

- Applicant argues that the present invention relates to yeast strains that are freeze-tolerant and capable of raising both sweet and lean doughs and additionally the isobutyric acid content below 150 ppm of the dry weight of the cells.
- a. The baker's yeast (*S. cerevisiae*) disclosed by R1 has the attributes of low temperature tolerance and high sugar tolerance. It is also agreed that R1 is silent regarding the isobutyric acid content. However, there is no data to indicate that the isobutyric content of the yeast disclosed by R1 is more than what is presently claimed. Further, the isobutyric acid is a volatile acid and as such it does not withstand the high baking temperatures. Again data regarding the presence of isobutyric acid in baked goods and the consequences, of having more that certain levels, on the organoleptic properties of baked products is not available.

It is noted that volatile fatty acids such as isobutyric acid have been investigated for their effect on the taste and aroma of wines and they may play a role in wine making. Moreover, such a volatile acid may affect the taste of yeast extract prepared from yeasts of higher isobutyric acid content.

While the data in Table 3 (page 16 instant specification) clearly show the difference between strain FT-4 and other commercial baker's yeasts regarding the isobutyric acid content, their significance on the taste and aroma of baked goods is lacking. The applicants compared bread doughs made with different yeasts for offensive taste and

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odor. Fig. 2 of the instant specification compares the doughs and not the baked product.

There is no data to suggest that the use of FT-4 strain in the dough results in improved taste and aroma.

Given the volatility of isobutyric acid at baking temperatures, it does not seem to play an important role in the taste and aroma of the final baked product.

In wine making art, the fermentation of must containing abundant sugar leads to wine with lower fatty acid concentration including isobutyric acid. Therefore, the adaptation to high sugar environments through hybridization and/or recombinant technology may have the isobutyric acid lowering effect.

The data in Table 6 (page 18, instant specification) is concerned with the fermentability of doughs. The examiner is assuming those figures in Table 6 to be the volume of carbon dioxide evolved in the course of fermentation. Table 6 is not concerned with isobutyric acid in yeast.

In conclusion, the inherency of low isobutyric acid concentration in freeze-tolerant and high sugar tolerant yeasts is a fair statement.

Conclusion

 Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within Art Unit: 1794

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-T 5:30 to 4:30 (Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr Examiner Art Unit 1794

/Callie E. Shosho/ Supervisory Patent Examiner, Art Unit 1794